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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,361	09/12/2003	David A. Mackiewicz	ENDOS 64949 (4164P)	6762

24201 7590 03/27/2008

FULWIDER PATTON LLP
HOWARD HUGHES CENTER
6060 CENTER DRIVE, TENTH FLOOR
LOS ANGELES, CA 90045

EXAMINER	
HOUSTON, ELIZABETH	
ART UNIT	**PAPER NUMBER**
3731	

MAIL DATE	DELIVERY MODE
03/27/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/661,361	MACKIEWICZ ET AL.	
	Examiner	Art Unit	
	ELIZABETH HOUSTON	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-15,17,18,21,32 and 34-42* is/are pending in the application.

4a) Of the above claim(s) *34-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-15,17,18,21,32 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/11/08 has been entered.

Election/Restrictions

2. Claims 34-41 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 34-41 are directed to a method of making the apparatus that were not presented in the original set of claims. Had they been originally presented, a restriction requirement would have been called for. Despite applicant's assertion that the claims should be examined, examiner respectfully disagrees. The product as claimed can be made with a materially different process such as welding, swaging or crimping. The process as claimed can be used to make a materially different product such as one that does not have V-shaped openings and mounting regions or one where the mounting region and the opening are the same size.

3. Since applicant has received an action on the merits for the original invention (elected species of apparatus vs. method of making), this invention has been

constructively elected by original presentation for prosecution on the merits. **Accordingly, claims 34-41 are withdrawn from consideration as being directed to a non- elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.**

The requirement is still deemed proper **and is therefore made FINAL**.

Claim Rejections - 35 USC § 102

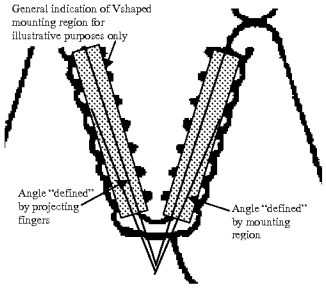
4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3, 6 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Goicoechea et al. (USPN 5,609,627)

6. Goicoechea discloses a stent comprising a structural body having a certain level of radiopacity (nitinol) and at least one marker holder integrally formed therein (Fig 4A, the marker holder is the two struts shown holding the marker (17)). The device comprises a radiopaque marker (17) attachable within the marker holder. The marker holder includes a pair of projecting fingers (each strut), which define a substantially V-shaped opening (space between the two struts). The radiopaque marker includes a substantially V shaped mounting region (the lumen of the coil and the inner surface of the coil are considered the mounting region, since that would be the portion of the marker that would mount onto or come in contact with the struts). The mounting region

fits within the opening defined by the fingers (note: claim does not require entirely within). (Alternatively the mounting region is only that portion of the coil that is physically inside the opening). The projecting fingers applying a force on the V-shaped mounting region (when the stent is expanded and the struts open the projecting fingers (struts) apply a force on the mounting region of the marker), which holds the radiopaque marker on the marker holder. The projecting fingers are connected at a notched region (peak of the undulation where the two struts meet), which allows the projecting fingers to move laterally to accept the radiopaque maker. Regarding claims 6 and 7 , the mounting region is consider to be all of the internal surface of the coil, and so, the angle, defined by the portion of the coil that is outside of the mounting region (17) has a larger angle that that of the opening.



7. Claims 2, 4, 6, 7, 32 and 33 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Goicoechea et al.

8. Goicoechea discloses the stent substantially as claimed as stated above. As to claims 2, 4, 6, 7, 32 and 33, Goicoechea teaches a radiopaque marker attached to the marker holder, but is silent as to how the marker is attached. The claimed phrase “by a heat weld” is being treated as a Product by Process limitation. As to claims 6 and 7, the

limitations that “the V-shaped opening defined by the projecting fingers defines a particular first angle when the pair of projecting fingers are unattached to the marker and the V shaped region of the radiopaque marker defines an angle which is larger than the angle of the V-shaped opening” and “the mounting region of the radiopaque marker larger than the opening defined by the projecting finger” are structural limitations that are directed toward the manufacturing process of the stent and are not directed toward the structure of the final product. As such these claims are also being treated as claiming Product by Process limitations. As set forth in the MPEP 2113, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (See MPEP § 2113). Examiner will thus evaluate the product claims without giving much weight to the method of its manufacture.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 8-15, 17, 18, 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goicoechea in view of Duerig et al (USPN 6,503,271).

11. Goicoechea discloses the device substantially as claimed as stated above except for the limitation that the radiopaque marker is made from a nickel-titanium alloy including a ternary element.

12. Duerig discloses a stent with radiopaque markers that are made form a nickel-titanium alloy with a ternary element that is platinum (Col 10, lines 15-23). Duerig further discloses that use of a micro-alloy is advantageous to overcome the challenge of galvanic corrosion (Col 4, lines 22-24).

13. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a micro allow into the invention of Goicoechea in order to provide an enhanced material that prevents galvanic corrosion.

14. Goicoechea discloses the stent substantially as claimed as stated above. As to claims 13, 14, 17, 19 and 21, Goicoechea teaches a radiopaque marker attached to the marker holder, but is silent as to how the marker is attached. The claimed phrase “by a heat weld” and “by melting” is being treated as a Product by Process limitation. As to claim 21, the limitations that “the V-shaped opening defined by the projecting fingers defines a particular first angle when the pair of projecting fingers are unattached to the marker and the V shaped region of the radiopaque marker defines an angle which is larger than the angle of the V-shaped opening” is a structural limitation that is directed toward the manufacturing process of the stent and is not directed toward the structure of the final product. As such this claim is also being treated as claiming a Product by

Process limitation. As set forth in the MPEP 2113, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (See MPEP § 2113). Examiner will thus evaluate the product claims without giving much weight to the method of its manufacture.

15. Regarding claim 10, Goicoechea in view of Duerig discloses the claimed invention except for the atomic percent of platinum. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide platinum in the percentage of between and including 2.5% and 15%, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch* 617 F.2d 272,205 USPQ 215 (CCPA 1980).

16. **Claims 1-4, 6, 7, 32 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frantzen (USPN 5,741,327) in view of Lee (US 6,520,934).**

17. Frantzen discloses a stent comprising a structural body having a certain level of radiopacity (nitinol) and at least one marker holder integrally formed therein (For example Fig. 11, 64, 67). The device comprises a radiopaque marker (96) attachable within the marker holder. The marker holder includes a pair of projecting fingers, which

define an opening (62). The radiopaque marker (94) includes a mounting region (96) The mounting region fits within the opening defined by the fingers The projecting fingers are connected at a notched region (for example Fig. 7, 68), which allows the projecting fingers to move laterally to accept the radiopaque maker. The marker is attached to the fingers by a heat weld (Col 7, L64).

18. Frantzen does not disclose that the projecting fingers apply a force. However Lee discloses several equivalent methods of securing radiopaque markers, including by adhesive, by swaging, by crimping, by soldering, or by spring-action tension fit.

19. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate spring action tension fit into the attaching method of the radiopaque markers. Frantzen discloses the claimed invention except for welding instead of the fingers applying a force to the marker. Lee shows that applying a force to secure a marker in place is an equivalent structure known in the art. Therefore, because the two techniques for attaching markers were art recognized equivalents at the time of the invention was made, one of ordinary skill in the art would have found it obvious to substitute the applying a force for the process of welding since substitution of one known element for another would have yielded predictable results. The combination results in projecting fingers that apply a force on the marker or expand to form a second expanded opening.

20. Frantzen does not explicitly disclose that the opening and the radiopaque marker are V-shaped. However, Frantzen does disclose that the “while the knob (94) is

preferably shown as round and matching the rounded space (62), various different matching patterns for the knob and rounded space could be successfully utilized… so long as the knob can be oriented within the rounded space" (C9: L43-49).

21. It would have been obvious to one having ordinary skill in the art at the time of the invention to alter the shape of the radiopaque markers and corresponding space to be V-shaped, since it is contemplated by the prior art that various shapes or patterns can be utilized without departing from the scope of the invention. Such a modification would have involved a mere change in the shape of a component, which is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

22. As to claims 6 and 7 and 42, the limitations that "the V-shaped opening defined by the projecting fingers defines a particular first angle when the pair of projecting fingers are unattached to the marker and the V shaped region of the radiopaque marker defines an angle which is larger than the angle of the V-shaped opening" and "the mounting region of the radiopaque marker larger than the opening defined by the projecting finger" and "to cause the fingers to move outwards to move the opening into a second expanded shape" are structural limitations that are directed toward the manufacturing process of the stent and are not directed toward the structure of the final product. As such these claims are also being treated as claiming Product by Process limitations. As set forth in the MPEP 2113, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the

product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (See MPEP § 2113). Examiner will thus evaluate the product claims without giving much weight to the method of its manufacture.

23. Claims 8-15, 17, 18 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frantzen in view in view of Lee and further in view of Duerig et al (USPN 6,503,271).

24. Frantzen modified by Lee discloses the device substantially as claimed as stated above except for the limitation that the radiopaque marker is made from a nickel-titanium alloy including a ternary element.

25. Duerig discloses a stent with radiopaque markers that are made form a nickel-titanium alloy with a ternary element that is platinum (Col 10, lines 15-23). Duerig further discloses that use of a micro-alloy is advantageous to overcome the challenge of galvanic corrosion (Col 4, lines 22-24).

26. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a micro allow into the invention of Goicoechea in order to provide an enhanced material that prevents galvanic corrosion.

27. As to claims 21, the limitations that "the V-shaped opening defined by the projecting fingers defines a particular first angle when the pair of projecting fingers are unattached to the marker and the V shaped region of the radiopaque marker defines an angle which is larger than the angle of the V-shaped opening" is a structural limitation that is directed toward the manufacturing process of the stent and is not directed toward the structure of the final product. As such this claim is also being treated as claiming a Product by Process limitation. As set forth in the MPEP 2113, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (See MPEP § 2113). Examiner will thus evaluate the product claims without giving much weight to the method of its manufacture.

28. Regarding claim 10, Frantzen modified by Lee and Duerig discloses the claimed invention except for the atomic percent of platinum. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide platinum in the percentage of between and including 2.5% and 15%, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch* 617 F.2d 272,205 USPQ 215 (CCPA 1980).

Response to Arguments

29. Applicant's arguments filed 06/20/07 have been fully considered but they are not persuasive. Regarding the new method claims, as stated above, the method claims have been restricted by original presentation of the claims and are directed toward an invention that is patentably distinct from the apparatus.

30. As reflected in the rejection above, Goicoechea, does in fact meet the limitation “projecting fingers applying a force on the V shaped mounting region" when the struts of the stent are being expanded during delivery of the stent.

31. Applicant's arguments with respect to the Frantzen reference have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./
Examiner, Art Unit 3731

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731